REMARKS

Claims 72-90, 93, and 96-102 are in this application. Claims 98-102 are new.

Claim 72 has been amended and claim 98 has been added. Claim 72 has been amended to define that the drug delivery system does not include an aqueous phase.

The drug delivery system of the invention contains a continuous hydrophobic gelled non-polymeric matrix, a discontinuous phase consisting of a polymer dissolved in a water soluble organic solvent and a therapeutic agent dispersed within the continuous phase.

It is clear from the specification that an aqueous phase is not present in the drug delivery system claimed in this application. This differs from other drug delivery systems that contain an aqueous phase. In Phillips v. AWH Corp., 75 USPQ2d 1369 (Fed. Cir. 2005), the Federal Circuit noted that in analyzing the language of the claims, the court must also consider the specification to see how the term in question is used there. The court noted that the specification is supposed to describe the invention. This being the case, one should be able to determine what a claim to that invention means by reading the specification.

As stated above, it is clear from the specification that an aqueous phase is not present in the drug delivery system and therefore, there is no legal or factual basis to require that the word "comprising" be replaced by "consisting of". This is supported by the following paragraphs of the specification (the first paragraph number being the paragraph number used in the original application and the second paragraph number (in parenthesis) being the paragraph number in the published application US 20030049320):

[0001] ([0001]) - According to this paragraph, the gelled composition comprises a polymer, an organic solvent, an oil and an emulsifier resulting in a ready-to-use, gelled,

syringeable, solution-in-oil dispersion. There is no disclosure nor suggestion of an aqueous phase.

Paragraph [00012] ([0012-0015]) states that the current invention addresses the need for a ready-to-use, stable, gelled, polymeric dispersion, encompassing a uniformly distributed biologically active, bioinactive agent or mixture thereof which is capable of rapidly forming in-situ, polymeric microcarriers of a controlled size, distribution and shape upon coming in contact with an aqueous medium. This clearly supports that the claimed drug delivery system does not include an aqueous component. If the drug delivery system of the invention included an aqueous component, then the polymeric microcarriers would already be formed and there would be no need to have the drug delivery system come into contact with an aqueous medium. This interpretation is supported by claim 72 which includes that the drug delivery system comprises non-preformed microparticles.

Further support for the fact that the drug delivery system claimed in this application does not contain an aqueous phase found in paragraph [0014] ([0016]) where it is stated that "On placing such a dispersion into a body where there is an aqueous component, a multitude of microcarriers is formed." Clearly, if there was an aqueous component in the claimed drug delivery system, the drug delivery system would not have to be put in contact with an aqueous component in order to form the microcarriers/ rnicroparticles.

Although it is stated in paragraph [00016] ([0018]) that water can be used as a solvent, this does not mean that an aqueous phase is present. This is evidenced by the remainder of the paragraph:

> Thus, for example, a solution of polymer in DMSO when emulsified into a solution of the nonionic emulsifier (sorbitan monosterate, sorbitan monopalmitate or a mixture thereof) in the oil at an elevated temperature and subsequently cooled, provides a true polymer droplet-in-the-oil dispersion. This dispersion is a viscous gel at

temperatures of 2-80°C but flows upon application of shear through a syringe-needle assembly. **Upon coming in contact with an aqueous medium, discrete microcarriers are formed. The presence of the nonionic emulsifier of the invention in this novel dispersion allows the formation of a ready-to-use microcarrier-forming composition which causes rapid emusification of the oil phase on contact with an aqueous medium.** (Emphasis added).

If there was an aqueous phase present in the drug delivery system, it would not be necessary to contact the claimed drug delivery system with an aqueous medium.

Other paragraphs of the specification that describe that the microcarriers are formed when the drug delivery system is contacted with an aqueous medium and are not formed sua sponte, including paragraphs [00018]; ([0020]); [00033], ([0035]); [00034], ([0036]); [00036], ([0083]), ([0089-0091]).

It is noted that in each reference cited by the Examiner, an aqueous phase is disclosed specifically. See pages 4-11 of the Office Action of May 3, 2006. Therefore, since no aqueous phase is present in the drug delivery system claimed in this application, it is respectfully requested the rejections based on the Mehta and Tominaga be withdrawn.

Support for claim 99 is found in paragraphs [00074] and [00075] of the application as originally filed. This describes adding a biologically active agent to the continuous phase.

Support for the claim 100 defining a method of using the drug delivery system according to this invention to treat prostate cancer is found in example 16 of the specification. The data in this example demonstrates rapid and prolonged suppression of serum testosterone levels. As described on page 716 in the accompanying article from Burton, et al., J. Biomaterial Science Polymer Edn. Vol. 11, No. 7, p. 715-729, leuprolide

acetate, when released in a continuous manner, significantly reduces serum testosterone levels which has implications in the treatment of several diseases such as prostate cancer, precocious puberty, endometriosis and mammary cancer.

Support for claim 101 defining a method of using the drug delivery system according to this invention to treat breast cancer is found on pages 39-40 and Figure 3 of the specification. It is well-known in the art that paclitaxel can be used to treat breast cancer. A copy of a package insert for Taxol (which is paclitaxel) is attached and this describes the use of Taxol for breast cancer.

Support for claim 102 defining a method of using the drug delivery system comprising poly L-lactic acid for its anti aging effect is found in example 25 and supported by the attached article J.B. Sterling et al. Poly-L-Lactic acid as a FacialFiller, Skintherapyletter.com, Vol. 10, 2005. As stated in the abstract of this article, "physicians use poly-L-lactic acid off-label to correct lipoatrophy associated with the normal aging process..."

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Janet I. Cord
c/o Ladas & Parry LLP
26 West 61st Street
New York, New York 10023
Reg. No. 33,778, (212-708-1935)